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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 1999D–2335]

Guidance for Industry and Food and Drug Administration Staff; Premarket Approval Applications for Absorbable Powder for Lubricating a Surgeon's Glove; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Premarket Approval Applications (PMA) for Absorbable Powder for Lubricating a Surgeon's Glove." This guidance describes the information FDA recommends that you provide in a PMA for absorbable powder for lubricating a surgeon's glove.

DATES: Submit written or electronic comments on this guidance at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled "Premarket Approval Applications (PMA) for Absorbable Powder for Lubricating a Surgeon's Glove" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 30, 1999 (64 FR 41744), FDA announced the availability of a draft guidance for comment entitled "Medical Glove Guidance Manual." (See *http://www.fda.gov/cdrh/dsma/135.html* for the draft guidance.) Elsewhere in the same issue of the **Federal Register** (64 FR 41710), FDA proposed that the 1999 draft guidance serve as a special control for class II gloves. However, chapter 4 of the 1999 draft guidance contained a section that discussed PMAs for absorbable powder for lubricating surgeon's gloves. Because the section discussing PMAs for absorbable powder is not relevant to class II gloves, FDA is removing this section and issuing it as a separate guidance document. FDA did not receive any comments on this section of the 1999 draft guidance. Because the recommendations in this section were available in draft form for comment, FDA is issuing this guidance as a final document. As with any guidance, however, you may submit comments at any time.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on PMAs for absorbable powder for lubricating a surgeon's glove. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive "Premarket Approval Applications (PMA) for Absorbable Powder for Lubricating a Surgeon's Glove" by fax machine, call the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800–899–0381, or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1230) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH

guidance documents is available at *http://www.fda.gov/cdrh/guidance.html.* Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets.*

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 USC 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket approval applications (21 CFR part 814, OMB control number 0910–0231). The labeling provisions addressed in the guidance have been approved by OMB under the PRA, OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding the guidance at any time. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments.* Submit two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 30, 2004

March 30, 2004.

Beverly Chernaik Rothstein

Beverly Chernaik Rothstein,
Acting Deputy Director for Policy and Regulations,
Center for Devices and Radiological Health.
[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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